K121352

510(k) Summary

The 510(k) Summary is submitted in accordance with 21 CFR §807.92 and the requirements of the Safe Medical Device Act (SMDA) of 1990.

AUG 15 2012

Submitter's Name	Abbott Vascular
Submitter's Address	3200 Lakeside Drive, Santa Clara, CA 95054
Telephone	(408) 845-0682
Fax	(408) 845-3743
Contact Person	Ivalee Cohen
Date Prepared	May 2, 2012
Device Trade Name	Armada 14 XT PTA Catheter
Device Common Name	PTA Catheter
Device Classification Name	Catheter, angioplasty, peripheral, transluminal, LIT
Predicate Device Names	• Abbott Vascular TREK OTW & MINI TREK OTW Coronary Dilatation Catheter (K103011, cleared 1/10/11 and K110617, cleared 6/2/11) • Abbott Vascular Armada 14 PTA Catheter (K102705, cleared 12/7/10)

Device Description

The Armada 14 XT PTA Catheter is an over-the-wire co-axial design with a balloon at the distal tip. The balloon segment expands to a known diameter and length at a specific inflation pressure and has radiopaque marker(s) under the balloon to aid in positioning the balloon in a stenosis. The co-axial shaft consists of a tubular inner and outer member. The inner lumen permits the use of a guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated. The outer lumen provides for inflation and deflation of the balloon with contrast fluid. Along the proximal portion of the shaft are brachial and femoral markers to aid in gauging the catheter's position relative to the guiding catheter tip when introducing the catheter through the guiding catheter. An adaption arm is located at the proximal end to provide access to the inflation lumen and guide wire lumen and allows connection with an inflation device.

Indication for Use

The device is indicated to dilate stenoses in femoral, popliteal, infra popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The 2.0 to 5.0 mm balloon diameters are also indicated for post-dilatation of balloon-expandable stents.

Technological Characteristics

The subject Armada 14 XT PTA Catheter has the same fundamental scientific technology (operating principle) and indication for use as the Armada 14 predicate device and shares the same materials, design, labeling, packaging materials, shelf life and sterilization process as the TREK and MINI-TREK predicate devices.

Performance Data

Performance testing was successfully completed on the Armada 14 XT PTA Catheter.

The following tests were conducted:

- Balloon Crossing Profile
- Refolded Balloon Profile
- Guide wire Lumen ID
- Total Catheter Length
- Minimum Balloon Burst Strength (Rated Burst Pressure, RBP)
- Balloon Compliance (Diameter vs. Pressure)
- Balloon Inflation/ Deflation Time
- Balloon Fatigue (Repeat Balloon Inflations)
- Tensile strength – Proximal Adaptation
- Tensile strength – Proximal Balloon Seal
- Tensile strength – Distal Outer Member to Proximal Shaft
- Tensile strength – Soft Tip to Inner Member Seal
- Catheter Flexibility & Kink Test
- Torque Strength
- Radiopacity
- Minimum Balloon Burst Strength (RBP) Within Stent
- Balloon Fatigue Within Stent (Repeat Balloon Inflations in Stent)
- Shelf Life (Accelerated Aging)

Biocompatibility testing included cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, hemolysis, pyrogen, and complement activation.

Conclusion

The *in vitro* bench and biocompatibility tests demonstrated that the Armada 14 XT PTA Catheters met all acceptance criteria and performed similarly to the predicate devices. No new safety or effectiveness issues were raised during the testing program and, therefore, these devices may be considered substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 15 2012

Abbott Vascular
c/o Ivalee Cohen
3200 Lakeside Drive
Santa Clara, CA 95054

Re: K121352
Trade/Device Name: Armada 14 XT PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT, DQY
Dated: May 02, 2012
Received: May 04, 2012

Dear Ms. Cohen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121352

Device Names: Armada 14 XT PTA Catheter

Indications for Use: The device is indicated to dilate stenoses in femoral, popliteal, infra popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The 2.0 to 5.0 mm balloon diameters are also indicated for post-dilatation of balloon-expandable stents.

Prescription Use___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121352